KRUUSE Borrelia Quick

Rapid test for detection of Borrelia antibodies in whole blood, serum or plasma.

Instruction Manual

KRUUSE Borrelia Quick, the rapid test for the detection of Borrelia antibodies in whole blood, serum and plasma.

Canine Lyme Disease

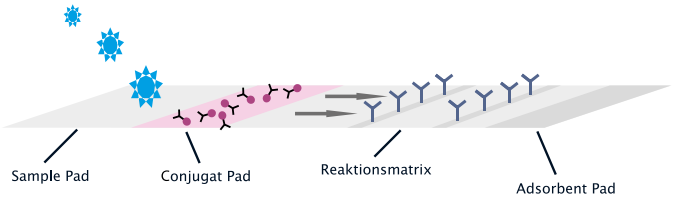
Lyme disease is one of the diseases transmitted by vectors (ticks). The pathogen Borrelia burgdorferi is a gram-negative, spiral-shaped and movable bacterium (spirochete). Worldwide, at least 13 genospecies belong to the Borrelia burgdorferi sensu lato (Bsl) complex. The three most important species B. burgdorferi sensu stricto (Bss), B. garinii (Bg) and B. afzellii (Ba) are also pathogenic for humans. For dogs, the pathogenicity of B. burgdorferi sensu stricto has been verified.
The natural reservoir for Borrelia is wild animals. Borrelia is transmitted by ticks of the species Ixodes ricinus. An infection does not always lead to immediate illness, it may take a long time (2-5 months) before clinical symptoms occur. cClinical signs of the disease in dogs often develop insidiously and can be nonspecific symptoms such as lethargy, lymphadenopathy and intermittent fever. A possible clinical manifestation is infection-related arthritis in one or more joints, sometimes with shifting leg lameness. Occasionally glomerulopathies occur. Even with effective antibiotic therapy a complete elimination of the pathogens is difficult.

Explanation of the Testing Process

KRUUSE Borrelia Quick rapid assay is a sandwich immunoassay which is developed for professional use by veterinarians. The gold-labeled immunoglobulin complexes are transported by capillary action with the fluid across the membrane and bind to immobilized antigens in the test region of the test strip.
With a positive test result, i.e. with the presence of specific antibodies against the Borrelia antigen, an aggregate builds in the test region consisting of antigen, anti-Borrelia antigen-antibody and the gold-labeled detection antibody and thus forms a colored line. If no colored line shows in the test region, the test result is negative. In both cases, a coloured line in the control region is visible. This indicates correct testing process of the KRUUSE Borrelia Quick.

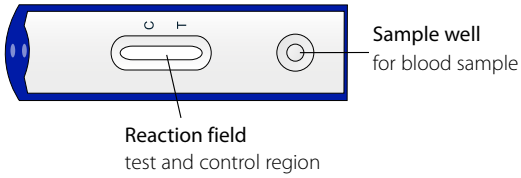
Upon application to the test strip Borrelia antibodies in the sample material react with the gold labelled antigens in the conjugate pad. The fluid then migrates up the strip by capillary action. In the test line region the Borrelia antigen-antibody gold marked complexes are captured by the immobilised capture reagents so that a red line is generated. The presence of a red line in the test line region indicates a positive result. If the sample does not contain Borrelia antibodies, no line will form in the test line region. Additionally, a red line must form in the control line region, independently of the presence of Borrelia antibodies in the specimen.

The control line serves as an internal control and indicates that sufficient sample fluid has been applied to the test strip and that proper wicking of the membrane has occurred.



The Test Cassette

The test strip is located behind the plastic cover. The sample well is on the right side. The reaction field is located in the middle of the test cassette. The test and the control region are located in the reaction field. The labelling next to the reaction field shows the test and control region.



CAUTION

- Only for veterinary and professional use
- For single use only
- Use the test cassette within 10 minutes of opening
- Please use an appropriate amount of sample
- Do not apply sample solution to the reaction field
- Avoid cross reactions by using a new sample tube for each sample
- Do not touch the reaction field
- Use only the original buffer provided in the kit
- Sample material could be infectious. Be careful with waste disposal
- Do not use cassettes after the expiry date
- Do not use the test if the packaging is damaged
- Consider the test results as invalid after the indicated time

Reagents, Materials, Instruments

I. Contents

- 5 test cassettes with pipette and drying pad
- 5 sample tubes
- 1 bottle with 2.5 ml reagent buffer
- 1 instruction manual

II. Additional Necessary Equipment

- Timer

Sample Preparation

KRUUSE Borrelia Quick was developed for examination of whole blood, serum or plasma.

General recommendations for blood samples

- Separate serum or plasma from blood as soon as possible to avoid haemolysis
- Heparin or EDTA blood can be used for the plasma extraction
- Use only clear, non-haemolyzed specimens
- Use of whole blood my decrease the sensitivity of the test result

Testing should be performed immediately after sample collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8° C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Bring specimens to room temperature prior to testing.
Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. If specimens are to be shipped, they should be packed in compliance with local transportation regulations for etiologic agents.

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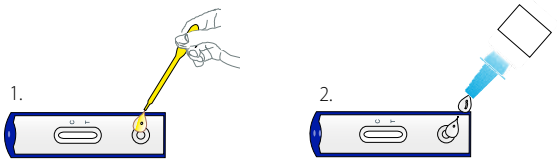
Test Procedure for Serum and Plasma

1. Take a blood sample and prepare the serum or plasma sample. Open the pouch; remove the pipette and pick up the sample material with the pipette.
   Apply one drop of serum or plasma with the pipette into the sample well. Wait a few seconds until the sample fluid is completely absorbed.

2. Open the buffer and add 2 drops of the buffer into the sample well.

If the liquid is not running well up the strip after 1,5 minute, add an additional drop of buffer into the sample well.

3. Read the results within 5-10 minutes of starting the test.



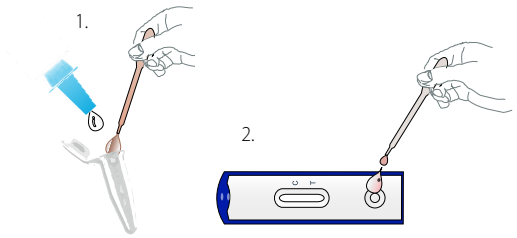
Test Procedure for Whole Blood

1. Take a blood sample. Open the pouch; remove the pipette and pick up the sample material with the pipette and place 1 drop of the whole blood into the sample tube.
   Open the buffer and add 3 drops of the buffer into the sample tube

2. Close the sample tube and shake it gently. Open the sample tube again and pick up the sample material with the pipette. Slowly apply 2 drops of the sample material with the pipette into the sample well (add the first drop to the sample well, wait a few seconds until the drop is absorbed, then add the second drop)

If the liquid is not running well up the strip after 1,5 minute, add an additional drop of buffer into the sample well.

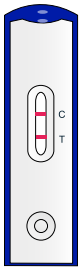
3. Read the result within 5-10 minutes of starting the test.



Test Evaluation

The results of the test can be read 5-10 minutes after starting the test.

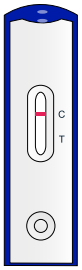
Note: A detection of antibodies in the sample material is not possible until 3-4 weeks after infection.



Positive Result

The test is positive when the control line (C) and the test line (T) are visible in the reaction field.
Antibodies against Borrelia antigen are detected in the sample material.
If a faint test line appears, the test result is still positive.
The red colour in the test region will vary depending on the concentration of Borrelia antibodies present in the sample material.

Attention: It is possible with KRUUSE Borrelia Quick to distinguish between natural exposure and vaccination antibodies. A serological test for antibodies against Borrelia should always be interpreted in relation with the clinical symptoms.



Negative Result

The test is negative when only the control line (C) is visible.
The test is negative when only a control line appears in the reaction field and there is no weakly defined test line visible. No Borrelia antibodies were detected in the sample material.

Invalid Result

If no control line is visible after the test was performed, the test is invalid. In this case, the test might not have been correctly carried out, the test may have passed the expiry date or the test was exposed for too long to ambient air outside the sealed pouch. If this occurs, a new test must be conducted.

ATTENTION: The result must be read within 10 minutes of starting the test. The test and the result are considered as invalid after that period.

Remarks: The test result should always be judged in connection with the anamnestic response and clinical context. All test results obtained with whole blood samples, which do not correlate with the clinical picture, should be repeated with a plasma or serum sample, as test of whole blood may decrease the sensitivity of the test result.

Storage

KRUUSE Borrelia Quick must be stored at room temperature (2°C to 30°C).

Disposal

A safe disposal is recommended. Sample material and test cassettes should be collected in a sealable plastic bag.

Test Performance Characteristics

KRUUSE Borrelia Quick	IgG ELISA, IgM ELISA, ImmunoBlot	
	Sensitivity	Specificity
Borrelia antibodies	95,83 %	94,12 %

References

1) R. K. Straubinger, N. Pantchev (2010): „Die Lyme-Borelliose-Impfung beim Hund-kontrovers diskutiert", Kleintier Konkret, Enke Verlag, Stuttgart, 5:8-11.
2) H. J. Selbitz, U. Tryen, P.V. Weigand (2010): „Medizinische Mikrobiologie, Infektions- und Seuchenlehre", 9. Aufl. Enke Verlag, Stuttgart.
3) Gary P. Worms and Ira Schwartz (2009): "Antibiotica Treatment of animals infected with Borrelia burgdorferi", Clinical microbiology reviews, July 2009, 387-395.

Symbols Used

2	Only for one use		Read user instruction carefully
Σ	Content	+4°C +30°C	Storage temperature
LOT	Lot number		Expiry date

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